DETAILED ACTION

Claims 1-12, 15 and 16 are withdrawn. Claims 13, 17 and 20 are cancelled. Claims 14, 18, 19 and 21 are under examination.

Withdrawn rejections:

Applicant's amendments and arguments filed on 4/13/11 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed below is herein withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 14, 18, 19 and 21 remain/are rejected under 35 U.S.C. 103(a) as being unpatentable over Pflaum (US 6740775) in view of Yoshioka et al. (Stability of drugs and dosage forms; 2000, springer, 268 pages; pp116-117).

Applicant claims a stabilized pharmaceutical composition in the form of a tablet comprising a polymorph form of pravastatin sodium and microcrystalline cellulose.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Pflaum teaches pharmaceutical compositions of the sodium salt of pravastatin in a crystalline form and methods of making them (claims 1-19). The X-ray diffraction pattern in Figure 2; shown below:

Figure 2

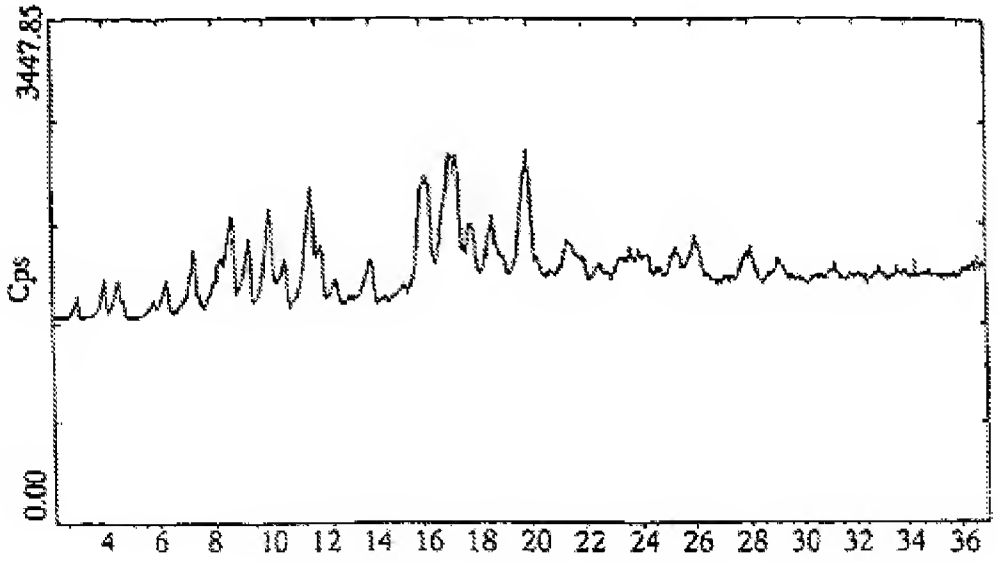

FIG. 2 is a diffractogram of crystals of the sodium salt of pravastatin prepared according to Example 2 of the present invention, which are scanned on the X-ray powder diffractometer within 2 to 48° 2Θ range with a 0.035° 2Θ step and an integration time of 1 second/step.

Applicant teaches that the instantly claimed process produces crystalline pravastatin sodium substantially similar to figure 2 above (original claim 9) and thus has the essentially same X-ray diffraction pattern with significant peaks and half value widths which equates the prior art product with that which is instantly claimed. From the instant specification [0003]: "For instance, crystalline pravastatin sodium is disclosed in U.S. Pat. No. 6,740,775 ("Form LEK")". **Tablets are taught** (column 5, lines 23-25 and column 6, lines 3-9). Pflaum directs the ordinary artisan to add microcrystalline cellulose no less than three times as for different functions (column 5, lines 27-43)(Examiner added emphasis): "The pharmaceutical formulation of this invention may comprise, in addition to the sodium salt of pravastatin, one or more fillers, such as **microcrystalline cellulose**, lactose, sugars, starches, modified starch, mannitol, sorbitol and other polyols, dextrin, dextran and maltodextrin, calcium carbonate, calcium phosphate and/or hydrogen phosphate, sulphate, one or more binders, such as lactose, starches, modified starch, dextrin, dextran and maltodextrin, **microcrystalline cellulose**, sugars, polyethylene glycols, hydroxypropyl cellulose, hydroxypropyl methylcellulose, ethylcellulose, hydroxyethyl cellulose, methylcellulose, carboxymethyl cellulose, gelatin, acacia gum, tragacanth, polyvinylpyrrolidone, magnesium aluminium silicate, one or more disintegrating agents such as croscarmellose sodium, cross-linked

polyvinylpyrrolidone, cross-linked carboxymethyl starch, starches and **microcrystalline cellulose**,". Since the claim language is open, then any and all ratios of pravastatin sodium to microcrystalline cellulose are included in the disclosure of Pflaum.

Pflaum teaches methods of making the pravastatin in the presence of ethanol or methanol in column 4, lines 26-52 reproduced below:

> The process for the preparation of crystals according to the present invention as described above comprises the following steps:
>
> (a) Providing a solution containing pravastatin and sodium cations in a lower aliphatic alcohol. This is suitably carried out by dissolution of an solid and/or amorphous sodium salt of pravastatin in a lower aliphatic alcohol having preferably 1 to 4 carbon atoms. More preferably, the alcohol used for the dissolution of pravastatin sodium is ethanol or methanol. The best crystallization results have been achieved when preparing a solution of pravastatin sodium in methanol.
>
> (b) Adding ethyl acetate into the alcoholic solution, preferably while the alcoholic solution obtained in step (a) is stirred continually. The addition of ethyl acetate into the alcoholic solution of pravastatin sodium is preferably carried out slowly, while the addition may be continuously or stepwise.
>
> (c) Cooling the resulting alcohol/ethyl acetate mixture; and
>
> (d) Crystallizing the sodium salt of pravastatin.
>
> In step (d) from the cooled mixture crystals of the sodium salt of pravastatin, which preferably have a colorless or pale yellow appearance and are in the form of needles or radiating clusters, are formed.
>
> Additionally, the crystals obtained by this process may preferably be filtered, ethyl acetate washed and dried.

Thus, the 'wet phase' comprises alcohol. Since the pravastatin sodium has to dissolve in the methanol, it is then reasonable to assert that there is more methanol present than pravastatin such that the ratio of pravastatin to alcohol is greater than one. Pflaum teaches a process of preparing the sodium salt of pravastatin using open language (claim 6).

Please note that the limitations in claim 14 concerning "occurs at least in a wet phase" and "wherein the wet phase comprises alcohol and the ratio of pravastatin sodium to alcohol is greater than one" of instant claim 18 or "wherein at least a wet phase, the ratio of pravastating sodium to microcrystalline cellulose is at least two" of instant claim 21 reads on a product by process. Please note that in product-by-process claims, "once a product appearing to be substantially identical is found and a 35 U.S.C. 103 rejection [is] made, the burden shifts to the applicant to show an unobvious difference." MPEP 2113. This rejection under 35 U.S.C. 103 is proper because the "patentability of a product does not depend on its method of production." *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985). As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972). That pertains to the functional language of a solid form subjected to accelerated stability testing remains stable after one month after being prepared as well. The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicants' pravastatin sodium differs and, if so, to what extent, from that of the discussed reference. Therefore, with the showing of the reference, the burden of establishing non-obviousness by objective evidence is shifted to the Applicants.

Yoshioka et al. teach that excipients such as microcrystalline cellulose absorb water and decrease degradation of drug tablets (pages 116-117 in part).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

1. The difference between the instant application and Pflaum is that Pflaum do not expressly teach a weight ratio of pravastatin sodium to microcrystalline cellulose of greater than 1.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to add a weight ratio of pravastatin sodium to microcrystalline cellulose of greater than 1 to the composition of Pflaum and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because: Pflaum teaches adding microcrystalline cellulose to the formulation but simply does not disclose the weight ratio. With regards to the weight ratio, it is the position of the Examiner that this is merely a matter of routine optimization. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of

ingredient amounts would have been obvious at the time of applicant's invention. From MPEP 2144.05: "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

The composition would be intrinsically stabilized against converting into one exhibiting peaks having half value widths of significant peaks above 2 degree 2 Theta in the absence of evidence to the contrary. As taught by Yoshioka et al, it is expected that drug tablets with microcrystalline cellulose to be more resistant to degradation because the microcrystalline cellulose absorbs water that can degrade the drug thus providing further motivation to add microcrystalline cellulose. *In other words, the expected result of adding microcrystalline cellulose to the pravastatin tablet is enhanced stability to degradation by water/humidity*.

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to argument:

Applicant asserts that Pflaum's teachings with regard to compositions comprising that polymorph are completely generic and that Pflaum provides no specific guidance as to how to provide a stabilized pharmaceutical composition, let alone a tablet and that Pflaum does not recognize the problem addressed by the present invention. Respectfully, the Examiner cannot agree for the following reasons. First of all, Pflaum is aware of the stability issue and clearly states that it is an object of the invention to provide a sodium salt of pravastatin which has improved purity and stability (Column 2, lines 21-24). Applicant argues that Pflaum provides no hint of what ratio of pravastatin to microcyrstalline cellulose should be used in the wet phase or recognize obtaining tablets by wet granulation. Respectfully, that ratio of pravastatin to microcrystalline cellulose is the point of the 103 rejection above. Pflaum directs the artisan to using microcrystalline cellulose from a list of excipients and the burden is upon Applicant to show an unexpected result from the specific selection of microcrystalline cellulose in a side by side comparison with the composition of Pflaum. Applicant to this date has not provided such evidence and therefore the claims remain obvious.

Applicant directs the Examiner to examples 5 and 6 where 3 g pravastatin is mixed with 12.6 g and 12 g Avicel PH 112, respectively, and the resulting mixture contains pravastatin sodium form D. Applicant asserts that they discovered the conversion of form LEK to convert to form D. The Examiner notes that the X-ray diffractogram of US 6740775 Figure 2 is reported by Applicant to be the "LEK" form (instant specification page 4, paragraph 2) whereas form D is named in WO 0143723 in Figure 7. The Examiner also notes that examples 5 and 6 do not expressly disclose that

the starting material was form LEK. Nevertheless, the claims are not drawn to form D but generally to any polymorph form of pravastatin sodium which are fairly taught by Pflaum. It is also noteworthy to mention that examples 5 and 6 only state that the samples "contain pravastatin sodium in form D" but do not state the purity level or relative amount. The samples could reasonably contain other polymorphic forms of pravastatin as well. Moreover, it appears that *only* a very specific ratio of specific components achieves this result rather than the broadly claimed ratio of a polymorph form of pravastatin sodium and microcrystaline cellulose in a ratio of pravastatin sodium to microcrystalline cellulose greater than one.

Applicant asserts that the product by process of the claimed invention is not the same as the prior art because it has improved stability and general utility. Again, a side by side comparison has not been performed to assess the 'improved stability' and utility is not at issue. From MPEP 716.01(c) II: The arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965).

Respectfully, these arguments are not persuasive and the claims remain rejected.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a

whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 14, 18, 19 and 21 remain/are rejected under 35 U.S.C. 103(a) as being unpatentable over Keri et al. (WO 01/43723) in view of Yoshioka et al. (Stability of drugs and dosage forms; 2000, springer, 268 pages; pp116-117).

Applicant claims a stabilized pharmaceutical composition in the form of a tablet comprising a polymorph form of pravastatin sodium and microcrystalline cellulose.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Keri et al. teach novel forms of pravastatin sodium, methods of making and methods of using the pravastatin sodium (Abstract and claims 1-203). Tablets are disclosed and may contain diluents such as **microcrystalline cellulose** (page 13, lines 4-7). Capsules are also taught (page 13, lines 24-27). Please note that the limitations in claim 14 concerning "occurs at least in a wet phase" and “wherein the wet phase

comprises alcohol and the ratio of pravastatin sodium to alcohol is greater than one" of instant claim 18 or "wherein at least a wet phase, the ratio of pravastating sodium to microcrystalline cellulose is at least two" of instant claim 21 reads on a product by process. Please note that in product-by-process claims, "once a product appearing to be substantially identical is found and a 35 U.S.C. 103 rejection [is] made, the burden shifts to the applicant to show an unobvious difference." MPEP 2113. This rejection under 35 U.S.C. 103 is proper because the "patentability of a product does not depend on its method of production." *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985). As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972). That pertains to the functional language of a solid form subjected to accelerated stability testing remains stable after one month after being prepared as well. The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicants' pravastatin sodium differs and, if so, to what extent, from that of the discussed reference. Therefore, with the showing of the reference, the burden of establishing non-obviousness by objective evidence is shifted to the Applicants.

Yoshioka et al. teach that excipients such as microcrystalline cellulose absorb water and decrease degradation of drug tablets (pages 116-117 in part).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

1. The difference between the instant application and Keri is that Keri do not expressly teach a weight ratio of pravastatin sodium to microcrystalline cellulose of greater than 1.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to add a weight ratio of pravastatin to microcrystalline cellulose of greater than 1 obtain a stabilized pharmaceutical composition to the composition of Keri and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because: Keri teaches adding microcrystalline cellulose to the formulation but simply does not disclose the weight ratio. With regards to the weight ratio, it is the position of the Examiner that this is merely a matter of routine optimization. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention. From MPEP 2144.05: “[W]here the general conditions of a claim are disclosed in the prior art,

it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

The composition would be intrinsically stabilized against converting into one exhibiting peaks having half value widths of significant peaks above 2 degree 2 Theta in the absence of evidence to the contrary. As taught by Yoshioka et al, it is expected that drug tablets with microcrystalline cellulose to be more resistant to degradation because the microcrystalline cellulose absorbs water that can degrade the drug thus providing further motivation to add microcrystalline cellulose. *In other words, the expected result of adding microcrystalline cellulose to the pravastatin tablet is enhanced stability to degradation by water/humidity.*

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to arguments:

Applicant asserts Keri's description of formulations is general and broad, without any hint as what is used, apart that pravastatin forms can be formulated into a composition. Respectfully, the Examiner cannot agree because, for example, Keri

directs the artisan to make form D of sodium pravastatin by dissolving any solid form of sodium pravastatin and ultimately drying the composition to produce form D (claims 186 and 201; Examples 5-7, pages 16-17; and Example 23, pages 22-23). Pravastatin sodium form D is claimed (claim 28) and pharmaceutical compositions are claimed (claims 5 and 29-33). No side by side stability evidence of unexpected results has been presented by Applicant. From MPEP 716.01(c) II: The arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965).

Applicant does not take well the Examiner's routine optimization argument. Applicant has directed the Examiner in the Remarks to the instant specification examples 5 and 6 where 3 g pravastatin is mixed with 12.6 g and 12 g Avicel PH 112, respectively, and the resulting mixture contains pravastatin sodium form D which is the same form taught by Keri and is therefore not novel. It is also noteworthy to mention that examples 5 and 6 only state that the samples "contain pravastatin sodium in form D" but do not state the purity level or relative amount. The samples could reasonably contain other polymorphic forms of pravastatin as well. Moreover, it appears that *only* a very specific ratio of specific components achieves this result rather than the broadly claimed ratio of a polymorph form of pravastatin sodium and microcrystaline cellulose in a ratio of pravastatin sodium to microcrystalline cellulose greater than one.

It remains the Examiner's position that Keri directs the artisan to make tablets with microcrystalline cellulose and Keri directs the artisan to make pharmaceutical compositions of sodium pravastatin form D. It seems to the Examiner that the expected

result of mixing sodium pravastatin form D with microcrystalline cellulose to make a tablet is a tablet of sodium pravastatin form D with microcrystalline cellulose that intrinsically has the stability as claimed no matter what method steps were used to arrive at the tablet of sodium pravastatin and microcrystalline cellulose.

Respectfully, these arguments are not persuasive.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 14, 18, 19 and 21 remain/are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 7, 14, 17, 18, 19, 25, 32, 33, and 39 of U.S. Patent No. 6680341 in view of Pflaum (US 6740775) and

Yoshioka et al. (Stability of drugs and dosage forms; 2000, springer, 268 pages; pp116-117).

The references of Pflaum and Yoshioka et al. are discussed in detail above and those discussions are hereby incorporated by reference. The instant subject matter embraces or is embraced by the copending subject matter. US 6680341 teaches stable/stabilized pharmaceutical formulations of sodium pravastatin and fillers. The disclosure encompasses all polymorphs of sodium pravastatin.

US 6680341 does not expressly teach the filler to be microcrystalline cellulose of a particular particle size and ratio with the active.

However, the art teaches using microcrystalline cellulose in sodium pravastatin formulations and the art teaches microcrystalline cellulose within the instant particle size. It would be obvious to use microcrystalline cellulose in the stable/stablized pravastatin formulations taught in 6680341 because the art suggests doing so. With regards to the weight ratio of ingredients; the amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention. Please note that in product-by-process claims, once a product appearing to be substantially identical is

found and a 35 U.S.C. 103 rejection [is] made, the burden shifts to the applicant to show an obvious difference. MPEP 2113. This rejection under 35 U.S.C. 103 is proper because the "patentability of a product does not depend on its method of production." *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985).

Thus, one of ordinary skill in the art would have recognized the obvious variation of the instant invention over the patent in view of the cited references.

2. Claims 14, 18, 19 and 21 remain/are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 12, 13, and 17 of U.S. Patent No. 6531507 in view of Pflaum (US 6740775) and Yoshioka et al. (Stability of drugs and dosage forms; 2000, springer, 268 pages; pp116-117).

The references of Pflaum and Yoshioka et al. are discussed above and those discussions are hereby incorporated by reference. The instant subject matter embraces or is embraced by the copending subject matter. US 6531507 teaches pharmaceutical formulations of sodium pravastatin and fillers. The disclosure encompasses all polymorphs of sodium pravastatin and is open to the addition of ingredients.

US 6531507 does not expressly teach the filler to be microcrystalline cellulose of a particular particle size and ratio with the active.

However, the art teaches using microcrystalline cellulose in sodium pravastatin formulations and the art teaches microcrystalline cellulose within the instant particle size. It would be obvious to use microcrystalline cellulose in the pravastatin formulations taught in US 6531507 because the art suggests doing so. With regards to the weight ratio of ingredients; the amount of a specific ingredient in a composition is clearly a

result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention. Please note that in product-by-process claims, once a product appearing to be substantially identical is found and a 35 U.S.C. 103 rejection [is] made, the burden shifts to the applicant to show an obvious difference. MPEP 2113. This rejection under 35 U.S.C. 103 is proper because the "patentability of a product does not depend on its method of production." *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985).

Thus, one of ordinary skill in the art would have recognized the obvious variation of the instant invention over the patent in view of the cited references.

Response to arguments:

Applicant's asserts that with respect to the rejections above that the cited patents do not provide direction to the artisan for selecting microcrystalline cellulose and the recited polymorph and is more than just routine optimization to arrive at the instant ratio of ingredients. Respectfully, the Examiner cannot agree because no unexpected or surprising results have been demonstrated and the instant claims are broader in scope than argued by Applicant.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERNST V. ARNOLD whose telephone number is (571)272-8509. The examiner can normally be reached on M-F 7:15-4:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Kwon can be reached on 571-272-0581. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ernst V Arnold/
Primary Examiner, Art Unit 1613